

REMARKS/ARGUMENTS

Claims 15-19 and 23-35 are pending. Claims 1-14, 20-22, and 26-28 were previously canceled and claim 15 is amended herein. No new matter is added by way of the amendment to claim 15. Reconsideration of this Application and entry of this Amendment is respectfully requested.

35 U.S.C. §103 Rejections

Claims 15-19 and 23-25 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Garnett (U.S. 6,162,511) or Baudin (WO 02/48202), in view of Tortorello (U.S. 6,107,361) or Takeuchi (6,558,799). Applicants respectfully traverse.

To maintain a proper rejection under 35 U.S.C. §103, the Office must meet four conditions to establish a *prima facie* case of obviousness. First, the Office must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the Office must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant's disclosure. Third, the prior art must teach or suggest all the claim limitations. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Fourth, if an obviousness rejection is based on some combination of prior art references, the Office must show a suggestion, teaching, or motivation to combine the prior art references ("the TSM test"). *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). Following *KSR Int'l Co. v. Teleflex, Inc.*, this fourth prong of the *prima facie* obviousness analysis must not be applied in a rigid or formulaic way such that it becomes inconsistent with the more flexible approach of *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966); 127 S. Ct. 1727 (2007). It must still be applied, however, as the TSM test captures the important insight that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.* at 1741 (citing *United States v. Adams*, 383 U.S. 39, 50-52 (1966)). It is necessary to "show all of the limitations of the claims arranged or combined in the same way as recited in the claims." *Net Moneyin v. Verisign*, 545 F.3d 1359, 1368 (Fed. Cir. 2008).

As amended herein, claim 15 recites, in part, a durable hydrophilic biocompatible coating formulation for a medical device, wherein the coating comprises a first layer comprising the monomer wherein the monomer is capable of covalently attaching to the surface of the biomedical device and a second layer comprising a polymer that is covalently linked to the monomer layer. This amendment is fully supported on page 8, lines 6-10. As stated in the specification, although

the final coating is a chemically heterogeneous system, it comprises a layer of the monomer covalently attached to the underlying surface of the medical device and an outer layer comprised of a polymer of a different species and/or molecular weight. The result is that the outer layer comprises a matrix or network of differing chain lengths or a differing degree of molecular cross-linkage and entanglements of the polymers in the layer. These effects combine and give a coating that can swell on exposure to an aqueous environment to give the coated device a desired lubricity. None of the cited references alone or in combination teaches the claimed biocompatible coating.

Garnett discloses coatings and compositions. However, there is no teaching or suggestion in Garnett of a biocompatible coating wherein the coating comprises a first layer comprising the monomer capable of covalently attaching to the surface of the biomedical device and a second layer comprising a polymer that is covalently linked to the monomer layer.

Baudin discloses surface coatings that include surface active photoinitiators. However, Baudin does not teach or suggest a biocompatible coating wherein the coating comprises a first layer comprising the monomer capable of covalently attaching to the surface of the biomedical device and a second layer comprising a polymer that is covalently linked to the monomer layer.

Tortorello discloses solvent-free radiation curable, optical glass fiber coating. Tortorello does not teach or suggest a biocompatible coating wherein the coating comprises a first layer comprising the monomer capable of covalently attaching to the surface of the biomedical device and a second layer comprising a polymer that is covalently linked to the monomer layer.

Takeuchi discloses decorative materials with a stain and scratch resistant surface. Takeuchi does not teach or suggest a biocompatible coating wherein the coating comprises a first layer comprising the monomer capable of covalently attaching to the surface of the biomedical device and a second layer comprising a polymer that is covalently linked to the monomer layer.

Individually and combined, the cited references do not teach each claimed limitation. Therefore, a *prima facie* case of obviousness has not been established and Applicants respectfully request that the rejection under 35 U.S.C. § 103 be withdrawn.

Conclusion

For the foregoing reasons, Applicants believe all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-0221.

Respectfully submitted,

/Anthony A. Sheldon/
Anthony A. Sheldon
Registration No. 47,078
Attorney for Applicant

Medtronic Vascular, Inc.
3576 Unocal Place
Santa Rosa, CA 95403
Facsimile No.: (707) 543-5420